Attachment 16: Revised Product Chemistry Chapter

5/25/99

MEMORANDUM

SUBJECT: Methyl Parathion. PC Code 053501. List A Reregistration Case 0153.

Revised Product Chemistry Chapter for the Reregistration Eligibility

Decision. DP Barcode D252912.

FROM: K. Dockter, Chemist

Reregistration Branch 2

Health Effects Division [7509C]

THRU: Alan Nielsen, Branch Senior Scientist

Reregistration Branch 2

Health Effects Division [7509C]

TO: Dennis Deziel

Special Review and Reregistration Division [7508 C]

Attached is the revised Product Chemistry Chapter for the methyl parathion [O,O-dimethyl O-p-nitrophenyl phosphorothioate] RED. The chapter was assembled by Dynamac Corporation under the supervision of RRB2, HED. The data assessment has undergone secondary and tertiary review and has been revised to reflect Agency policies. Many product chemistry data requirements remain outstanding.

Attachment: Reregistration Eligibility Decision: Product Chemistry Considerations

cc: RF, Reg. Std. File, SF, Dockter, Locke, Cropp-Kohlligian, Dennis Deziel; SRRD.

RD/I: RRB2/T2 Methyl parathion RED Team: D. Locke, [the TL], B. Cropp-Kohlligian, K. Raffaele, R. Griffin.

7509C:RRB2:CM2:Rm712N:57886:KD/kd METHYL PARATHION.RED[896]

METHYL PARATHION PC Code 053501; Case 0153 (DP Barcode D252912)

Reregistration Eligibility Decision: Product Chemistry Considerations

May 20, 1999

Contract No. 68-D4-0010

Submitted to: U.S. Environmental Protection Agency Arlington, VA

> Submitted by: Dynamac Corporation 2275 Research Boulevard Rockville, MD 22850-3268

METHYL PARATHION

REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

PC Code 053501; Case No. 0153

DP Barcode D252912

DESCRIPTION OF CHEMICAL

Methyl parathion [O,O-dimethyl O-*p*-nitrophenyl phosphorothioate] is an insecticide used on a variety of vegetables, fruits, and field crops.

$$\begin{array}{c|c} O_2N & & S \\ & \parallel & \\ O & \stackrel{P}{\longrightarrow} OCH_3 \end{array}$$

Empirical Formula: C₈H₁₀O₅NPS

Molecular Weight: 263.2 CAS Registry No.: 298-00-0 PC Code: 053501

IDENTIFICATION OF ACTIVE INGREDIENT

Pure methyl parathion is a white crystalline solid with a melting point of 35-36 C, bulk density of 1.358 g/mL at 25 C, vapor pressure of 9.7 x 10^{-6} mm Hg at 20 C, and octanol/water partition coefficient (P_{ow}) of 3300. Methyl parathion is only slightly soluble in water (55-60 mg/L at 20 C); readily soluble in dichloromethane, 2-propanol, and toluene; and practically insoluble in n-hexane. Methyl parathion is formulated with inert ingredients for manufacturing use to produce an 80% tan-colored liquid.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 5/19/99 identified two methyl parathion manufacturing-use products (MPs) registered under PC Code 053501: an 80% formulation intermediate (FI; EPA Reg. No. 1812-399) registered to Griffin L.L.C. and an 80% FI (EPA Reg. No. 4787-28) registered to Cheminova Agro A/S. We note that REFS identifies these products as technical products (Ts); however, based on their CSFs, both are formulated from unregistered TGAIs and are thus

appropriately identified as FIs. The Cheminova 80% FI was registered to replace an identical product (EPA Reg. No. 4787-4) which was voluntarily canceled by Cheminova on 7/21/98. Only the Griffin and Cheminova unregistered TGAIs and 80% FIs (EPA Reg. Nos. 1812-399 and 4787-28) are subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

The Science Chapter of the Methyl Parathion Reregistration Standard dated 11/8/85 and the Methyl Parathion Guidance Document dated 12/8/86 required additional generic and product-specific product chemistry data for the registered methyl parathion MPs. The Methyl Parathion Reregistration Standard Update dated 11/24/92 reviewed data submitted in response to the Guidance Document and summarized the product chemistry database in support of the reregistration of methyl parathion. The Update required additional product chemistry data concerning OPPTS 830.1600-1650, 1670, 7000, 6314, 6315, 6316, 6317, 6319, 6320, and 7100 for the Cheminova TGAI and 80% FI (EPA Reg. No. 4787-4). Although the Cheminova 80% FI (EPA Reg. No. 4787-28) was registered following issuance of the Methyl Parathion Update, data submitted for EPA Reg. No. 4787-4 will apply to data requirements for EPA Reg. No. 4787-28 because the products are identical. The full complement of product chemistry data pertaining to the Griffin 80% FI (EPA Reg. No. 1812-399), which was also registered (4/20/98) following issuance of the Update, have been submitted and are under review.

A Data Call-In dated 6/87 was issued to registrants of methyl parathion MPs requiring data concerning the potential for formation of halogenated dibenzo-p-dioxins/dibenzofurans during the manufacture of methyl parathion. Data remain outstanding.

The current status of the product chemistry data requirements for the Griffin and Cheminova methyl parathion unregistered TGAIs and MPs is presented in the attached data summary tables. Refer to these tables for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

All product chemistry data requirements except dissociation constant, octanol/water partition coefficient, solubility, and vapor pressure (OPPTS 830.7370, 7550, 7840, and 7950) remain unfulfilled for the Griffin unregistered TGAI and 80% FI pending review of data submitted for this product. Pertinent data requirements remain unfulfilled for the Cheminova unregistered TGAI and 80% FI; additional data are required concerning the potential for formation of dioxins (OPPTS 830.1600, and 1620-1670) and physical/chemical characteristics including stability, oxidation/reduction, flammability, explodability, storage stability, miscibility, corrosion characteristics, pH, UV/visible absorption, and viscosity (OPPTS 830.6313, 6314, 6315, 6316, 830.6317, 6319, 6320, 7000, 7050, and 7100). When the outstanding dioxin data have been received, the Agency will determine if further analytical quantitation of halogenated dibenzo-p-

dioxins/dibenzofurans is required. Provided that the registrants submit the data required in the attached data summary tables for the unregistered TGAIs and 80% FIs, and either certify that the suppliers of beginning materials and the manufacturing processes for the methyl parathion MPs have not changed since the last comprehensive product chemistry reviews or submit complete updated product chemistry data packages, HED has no objections to the reregistration of methyl parathion with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s).: 3107

Subject: EPA Reg. No. 4787-4. Methyl Parathion Product Chemistry in

Response to the Methyl Parathion Registration Standard Data

Gaps.

From: S. Malak

To: A. Rispin/D. Edwards

Dated: 2/11/88 MRID(s): 40406601

CBRS No(s).: 3280

Subject: Methyl Parathion MP - EPA Registration No. 4787-4 Cheminova -

Response to the Product Chemistry Chapter.

From: G. Makhijani

To: D. Edwards and A. Rispin

Dated: 3/25/88 MRID(s): 40482401

CBRS No(s).: 3804

Subject: Methyl Parathion MP - EPA Registration No. 4787-4 Cheminova -

Response to the Product Chemistry Chapter.

From: G. Makhijani

To: D. Edwards and A. Rispin

Dated: 5/25/88 MRID(s): 40601501

CBRS No(s).: 4023

Subject: Methyl Parathion - Technical. EPA Registration No. 4787-4 -

Cheminova - Response to the Product Chemistry Chapter.

From: G. Makhijani

To: D. Edwards and A. Rispin

Dated: 8/3/88 MRID(s): None

CBRS No(s).: 6491

Subject: Product Chemistry Data Review for Technical Methyl Parathion to

Determine the Potential for Halogenated Dibenzo-p-

Dioxin/Dibenzofuran Formation.

From: S. Funk
To: E. Feris
Dated: 6/20/90

MRID(s): 40482401 and 40601501

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References (cited):

00055859 A/S Cheminova (1980) [Chemical Analysis of Methyl parathion]: Pr-4; CDL:243416-A)

00055860 A/S Cheminova (1980) Physical and Chemical Properties: [Methyl parathion]: Pr-Ch-mp-3. (Unpublished study received Sep 22, 1980 under 4787-4; CDL:243416-B)

00055866 A/S Cheminova (1980) Product Chemistry: Methyl parathion Technical: Pr-Ch-mp-3. (Unpublished study received Sep 22, 1980 under 4787-4; CDL:243416-M)

40406601 A/S Cheminova (1987) Product Chemistry - Methyl Parathion Technical: Study No. KLy/870625-MP3. Unpublished study. 17 p.

40482401 A/S Cheminova (1987) Product Chemistry - Methyl Parathion Technical ... Supplementary Information ...: Study No. MVF/01.12.87-MP-3. Unpublished study prepared by A/S Cheminova in association with the Ministry of the Environment, Denmark. 42 p.

40601501 A/S Cheminova (1987) Product Chemistry - Methyl Parathion Technical ...: Supplementary Information: Submission/Pr-Ch-MP-3-conf/-5/04.19.88. Unpublished study. 14 p.

The following MRIDs have been referenced by Griffin in support of the 80% FI (EPA Reg. No. 1812-399) and are currently under review:

42365505 Orr, G. (1992) Griffin Corporation Test Methods: Physical and Chemical Characteristics of Pesticide Products. Unpublished study prepared by Griffin Corp. 25 p.

42869302 Hand, O. (1993) Griffin Corporation Test Methods: Physical and Chemical Characteristics of Pesticide Products: Kocide LF. Unpublished study prepared by Griffin Corp. 14 p

44279801 Harris, M. (1997) GX 507: Product Identity and Composition. Unpublished study prepared by Griffin Corp. 30 p. {830.1550, 830.1600, 830.1620, 830.1670}

44279802 Harris, M. (1997) GX 507: Physical and Chemical Properties: Lab Project Number: 97-003: P97-003. Unpublished study prepared by Griffin Corp. 28 p. {OPPTS 830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7000, 830.7050, 830.7100, 830.7200, 830.7220, 830.7300, 830.7520}.

44279803 Harris, M. (1997) GX 507: Report Amendment: (Density). Unpublished study prepared by Griffin Corp. 6 p. {OPPTS 830.7300}.

44279804 Harris, M. (1997) Griffin Analytical Methods: Methyl Parathion in Technical and Formulated Products: Capillary GLC Assay Method: Lab Project Number: TM-1198. Unpublished study prepared by Griffin Corp. 18 p. {OPPTS 830.1800}.

44317801 Harris, M. (1997) GX 507: Analysis and Certification of Product Ingredients: Lab Project Number: 97-003: P97-003. Unpublished study prepared by Griffin Corp. 19 p. {OPPTS 830.1700, 830.1750}.

Case No. 0153 PC Code 053501

Case Name: Methyl Parathion

Registrant: Griffin L.L.C.

Product(s): Unregistered TGAI and 80% FI (EPA Reg. No. 1812-399)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product identity and composition	N	44279801
830.1600	Description of materials used to produce the product	N	44317801
830.1620	Description of production process	N	44317801
830.1670	Discussion of formation of impurities	N	44279801
830.1700	Preliminary analysis	N	44317801
830.1750	Certified limits	N	44317801
830.1800	Enforcement analytical method	N	44279804
830.6302	Color	N	44279802, 42365505
830.6303	Physical state	N	44279802, 42365505
830.6304	Odor	N	44279802
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	N	44279802
830.6314	Oxidation/reduction: chemical incompatability	N	44279802, 42365505
830.6315	Flammability	N	44279802
830.6316	Explodability	N	44279802
830.6317	Storage stability	N	44279802, 42365505
830.6319	Miscibility	N	44279802
830.6320	Corrosion characteristics	N	44279802, 42365505
830.7000	рН	N	44279802, 42365505
830.7050	UV/Visible absorption	N	44279802
830.7100	Viscosity	N	44279802, 42869302
830.7200	Melting point/melting range	N	44279802
830.7220	Boiling point/boiling range	N	44279802
830.7300	Density/relative density/bulk density	N	44279802, 42869302
830.7370	Dissociation constants in water	Y	40406601 ³

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	00055860
830.7840	Water solubility: column elution method; shake flask method	Υ	40406601 ³
830.7950	Vapor pressure	Y	00055860

¹Y = Yes; N = No; N/A = Not Applicable. Data submitted by Cheminova pertaining to 830.7370, 7550, 7840, and 7950 were referenced by Griffin; these data may be used to fulfill requirements for the Griffin product provided their use has been approved by Cheminova.

² Italicized references are currently under review; **bolded** references were reviewed in the Methyl Parathion Reregistration Standard Science Chapter dated 11/8/85; and all other references were reviewed as noted.

³CBRS No. 3107, 2/11/88, S. Malak.

Case No. 0153 PC Code 053501

Case Name: Methyl Parathion

Registrant: Cheminova Agro A/S
Product(s): Unregistered TGAI and 80% FI (EPA Reg. No. 4787-28)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product identity and composition	Y	40482401 ³ , CSF 6/16/88 ⁴ , CSF 1/17/97 ⁵
830.1600	Description of materials used to produce the product	N ⁶	00055859, 00055866 , 40406601 ⁷
830.1620	Description of production process	N ⁶	00055859, 00055866 , 40406601 ⁷
830.1670	Discussion of formation of impurities	N ⁸	00055859
830.1700	Preliminary analysis	Y 9	00055859 , 40482401 ^{3,10} , 40601501 ¹⁰
830.1750	Certified limits	Υ	40482401 ³ , CSF 6/16/88 ⁴ CSF 1/17/97 ⁵
830.1800	Enforcement analytical method	Υ	00055859 , 40482401 ^{3,10} , 40601501 ^{10,11}
830.6302	Color	Υ	40406601 ⁷
830.6303	Physical state	Υ	40406601 ⁷
830.6304	Odor	Υ	40406601 ⁷
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	N ¹²	40406601 ⁷
830.6314	Oxidation/reduction: chemical incompatability	N	
830.6315	Flammability	N	
830.6316	Explodability	N	
830.6317	Storage stability	N	
830.6319	Miscibility	N	
830.6320	Corrosion characteristics	N	
830.7000	рН	N ¹³	40406601 ⁷
830.7050	UV/Visible absorption	N 14	
830.7100	Viscosity	N	

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.7200	Melting point/melting range	Υ	40406601 ^{7 5}
830.7220	Boiling point/boiling range	Υ	40406601 ⁷
830.7300	Density/relative density/bulk density	Υ	40406601 ⁷ , 40482401 ³
830.7370	Dissociation constants in water	Y	40406601 ⁷
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	00055860
830.7840	Water solubility: column elution method; shake flask method	Y	40406601 ⁷
830.7950	Vapor pressure	Υ	00055860

¹Y = Yes; N = No; N/A = Not Applicable. Data were originally submitted in support of the Cheminova 80% FI (EPA Reg. No. 4787-4) which has been canceled. Because EPA Reg. No. 4787-28 is identical to EPA Reg. No. 4787-4, all submitted data are applicable to the new FI.

²Bolded references were reviewed in the Methyl Parathion Reregistration Standard Science Chapter dated 11/8/85, and all other references were reviewed as noted.

³CBRS No. 3280, 3/25/88, G. Makhijani.

⁴CBRS No. 4023, 8/3/88, G. Makhijani.

⁵The CSF was obtained from the product jacket.

⁶Additional information is required by the Dioxin DCI dated 6/87 concerning the manufacturing conditions and starting materials which may promote the possible formation of halogenated dibenzo-<u>p</u>-dioxins/dibenzofurans during the manufacturing process.

⁷CBRS No. 3107, 2/11/88, S. Malak.

⁸Additional discussion is required by the Dioxin DCI dated 6/87 concerning the potential for formation of halogenated dibenzo-<u>p</u>-dioxins/dibenzofurans.

⁹On receipt of the outstanding manufacturing information and discussion of formation of impurities for dioxins, the Agency will determine if further analytical quantitation of halogenated dibenzo-p-dioxins/dibenzofurans is required.

¹⁰CBRS No. 6491, 6/20/90, S. Funk (for dioxins).

¹¹CBRS No. 3804, 5/25/88, G. Makhijani.

¹²Additional data concerning the stability of the TGAI in the presence of metals and metal ions are required.

¹³Data concerning the pH of the MP are required.

¹⁴The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.